Supreme Court, U.S.
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No. 01-660

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT BARR LABORATORIES, INC.

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QUESTIONS PRESENTED FOR REVIEW

1. Did the Federal Circuit err by finding double patenting through the straightforward application of 100 years of uniform precedent where Eli Lilly sought and obtained narrower patents for 12 years before requesting an all-encompassing patent monopoly on its basic invention – a monopoly-extending tactic that is no longer possible after a change in the law that Congress enacted in 1995?

2. Did the Federal Circuit err by noting in a footnote that Lilly could not resurrect its invalid patent by filing a post-judgment terminal disclaimer, particularly considering that Lilly had waived the issue by steadfastly refusing to file any such disclaimer throughout six years of litigation over the double-patenting issues?

CORPORATE DISCLOSURE STATEMENT

Respondent, Barr Laboratories, Inc. does not have any parent corporations or any publicly held company that owns 10% or more of the corporation's stock.

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INTRODUCTION

Nothing about the Federal Circuit's decision warrants Supreme Court review. Lilly cites no circuit conflict, no contrary Supreme Court precedent, no issue of national significance, and no constitutional issue. The Federal Circuit itself did not suggest that it was making new law or departing from established precedent in any way. Instead, the court found Lilly's '549 patent invalid for double patenting based on a standard analysis that the courts consistently have applied for over 100 years.

Far from an important issue, Lilly conceded below that its primary question presented has never arisen before and likely will never arise again. Nevertheless, in an attempt to craft an issue meriting Supreme Court review, Lilly does an about-face. It now argues that its primary question presented is significant because the Federal Circuit's decision purportedly will lead to "unhappy results" for our "nation's patent system." (Lilly Pet. at 24). But Lilly earlier told the Federal Circuit that despite "a review of nearly 500 double patenting decisions," it could not find any other case raising the same issue. (Lilly's 2nd Reh'g Pet. at 7). That once-in-a-century issue arose here only because of a confluence of unlikely events, the most significant of which was Lilly's 12-year delay in seeking a patent on what it now describes as its "basic" invention.

Not only did this issue never occur before, but it will never recur in the future. A change in the law prevents the issue from ever arising again. Lilly acknowledged as much below. It told the Federal Circuit that by changing the relevant law in 1995, Congress already "remed[ied]" the double-patenting "problem" that arises from "inordinate delays in the PTO." (Lilly Cross-Appellant Br. at 70). In fact, under the new law, the '549 patent would have expired eight years ago in 1994, thus completely eliminating the monopoly-extending double-patenting issues at the heart of this case.

The Federal Circuit's decision also is unassailable on the merits under long-settled law. To enforce the limited patent monopolies mandated by Congress and the U.S. Constitution, this Court and the appellate courts have held repeatedly that double patenting occurs when an applicant accepts a narrow patent covering a specific member of a class (*i.e.*, a "species" patent) before obtaining a broader patent covering the entire class (*i.e.*, a "genus" patent). That is precisely what happened here. In an effort to obtain an illegitimate monopoly extension through overlapping patents, Lilly first accepted the '213 patent covering a species (the administration of fluoxetine to treat anxiety) and later obtained the '549 patent covering the genus (the administration of fluoxetine for any purpose, including treating anxiety).

Because it does not contest that the '549 patent is invalid under a standard analysis, Lilly is forced to propose a new exception to the double-patenting doctrine that would be limited to the bizarre facts of this specific case – a "prior-art" exception based on a fortuitous public disclosure, which no court has ever before recognized in the doctrine's 100-year history. Lilly asserts that creating such an exception is necessary to address "unfairness" that may result from the delayed issuance of a genus patent. But the courts *already* have created an exception to address any such purported unfairness. That exception is called the "two-way test," which Lilly ignores and which the Federal Circuit correctly held did not apply in this case. Lilly does not even challenge that holding.

Lilly's second question presented – the terminal-disclaimer issue – is equally inappropriate for Supreme Court review. Once again, the issue is unlikely to arise again in the future. Lilly has cited no other case where, for the first time after a final judgment had been entered on appeal, a party attempts to resurrect an invalid patent by filing a terminal disclaimer. Lilly also waived this issue by failing to raise it below. That waiver was intentional; it was a strategic choice designed to obtain the longest possible

patent monopoly. It is too late now for Lilly to raise the issue for the first time in the Supreme Court.

The Federal Circuit also was correct on the merits of this issue. The Federal Circuit noted in a footnote that Lilly could not resurrect the '549 patent with a post-judgment terminal disclaimer, thus preempting any further delay tactics by Lilly. Lilly now asserts that the Federal Circuit's ruling contradicts the applicable statute. But the statute does not even expressly address double patenting. It merely permits patent owners to "disclaim" a portion of their monopoly, but does not state that doing so will avoid a double-patenting violation. *See* 35 U.S.C. § 253 (2001). Indeed, Lilly fails to cite even one case holding that a patent owner may resurrect a patent *already* declared invalid with a post-judgment terminal disclaimer – a result that would violate the long-recognized and deeply-rooted presumption of regularity that attaches to final judgments.

At bottom, Lilly is seeking Supreme Court review of fact-bound issues that never arose before and will never arise again. But certiorari jurisdiction is not designed "merely to give the defeated party . . . another hearing" (*Magnum Imp. Co. v. Coty*, 262 U.S. 159, 163 (1923)), or "for the benefit of the particular litigants" (*Rice v. Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955)). Thus, this Court should deny Lilly's certiorari petition.

COUNTERSTATEMENT OF THE CASE

I. Factual Background

A. Lilly Intentionally Delayed For 12 Years Before Seeking A Patent On Its Basic Invention.

Lilly filed its first patent application on fluoxetine in 1974. (Lilly App. at 3a). What followed, as the Federal Circuit noted, was "a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy." (*Id.* at 4a). If not for the Federal Circuit's decision, this "Hapsburg legacy" of patents would have resulted in a 26-year monopoly on the use of fluoxetine to treat depression (*id.* at

85a), rather than the 17 years then mandated by the Patent Code. *See* 35 U.S.C. § 154 (1994), *amended by* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4983 (1994). The Federal Circuit noted that this is "precisely the result that the doctrine of obviousness-type double patenting was created to prevent." (Lilly App. at 85a (internal quotation marks omitted)).

Lilly's extended monopoly resulted from a 12-year delay in seeking a patent on its so-called "basic" invention. (*See id.* at 4a). That basic invention was the discovery of fluoxetine's defining biological property – the blocking of uptake in the brain of a chemical known as "serotonin." (*Id.* at 26a). Because serotonin uptake blocking occurs whenever fluoxetine is administered to any patient for any reason, Lilly's '549 patent on that basic invention created a broad monopoly effectively covering *any* pharmaceutical use of the drug, including the treatment of depression and anxiety. (*Id.* at 29a).

Lilly's 12-year delay in requesting a patent on its basic invention was highly unusual. Normally, applicants seek patents on their basic invention *before* seeking patents on later-developed improvement inventions. But Lilly reversed the order here. In 1974, shortly after discovering fluoxetine's biological property, Lilly filed an application seeking a patent with narrow claims to the use of the compound to treat specific diseases. (*Id.* at 3a-4a). Although its 1974 application disclosed that fluoxetine was a serotonin uptake blocker, Lilly did not apply for a patent on that subject. (*Id.*).

During the next 12 years – without requesting a patent on its basic invention – Lilly continued to file applications, present claims, prosecute claims, and obtain patents relating to fluoxetine. (*Id.*). For instance, Lilly's 1974 application included claims covering the chemical compound itself, a sufficient dose of the compound to induce a psychotropic effect, and the use of the compound (and other compounds) to treat depression.

(J.A.00556).[1] These claims resulted in the issuance of three patents between 1977 and 1982. (J.A.00280-290; J.A.00291-300; J.A.00740-749). In 1980, Lilly filed another application claiming the use of fluoxetine to treat hypertension, which resulted in the issuance of another patent in May 1982. (J.A.00304-308). In 1983, Lilly filed yet another application claiming the use of fluoxetine to treat anxiety, which resulted in the issuance of the anxiety patent three years later in 1986. (J.A.00309-313).

Finally, in a March 1986 application – 12 years after its initial patent application – Lilly presented a broad, generic claim directed to fluoxetine's defining biological property. (Lilly App. at 7a-8a; *see also* J.A.00807-808; J.A.00849). The PTO promptly issued the '549 patent on that claim in December 1986. (Lilly App. at 7a). Contrary to Lilly's unsupported representation, Lilly's "broad, basic application" on serotonin blocking did not encounter any "examination complexities" that delayed issuance. (Lilly Pet. at 9). From beginning to end, the prosecution lasted only nine months from March 1986 to December 1986, which was markedly shorter than the typical multi-year patent prosecution. The "examination complexities" recounted in Lilly's petition all occurred *before* Lilly applied for the '549 patent in March 1986.

B. By Delaying For 12 Years, Lilly Sought To Artificially Extend The Monopolies Granted Through Earlier-Issued Fluoxetine Patents.

If not for the Federal Circuit's decision, Lilly's delaying tactic would have resulted in an extension of Lilly's monopoly rights under all of its earlier-issued fluoxetine patents. Before that decision, the '549 patent was scheduled to expire in December 2003, which was later than the scheduled expirations of Lilly's five other fluoxetine patents:

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1. References to "J.A.__" refer to the parties' joint appendix filed with the Federal Circuit on October 14, 1999.

Patent	Scheduled Expiration
depression	April 1994
psychotropic effect	April 1994
hypertension	October 2000
fluoxetine	February 2001
anxiety	May 2003
serotonin blocking	December 2003

(J.A.00291; J.A.00740; J.A.00280; J.A.00304; J.A.00312; J.A.00320). The '549 patent effectively extended all of the earlier patent terms because, as the Federal Circuit held in a now-uncontested factual ruling, serotonin blocking occurs whenever fluoxetine is administered to any patient for any reason. (Lilly App. at 29a). For instance, even though Lilly's depression patent expired in 1994, Lilly argued that the '549 patent precluded Barr from selling fluoxetine as an antidepressant until December 2003. If that argument were accepted, Lilly would have expanded its monopoly over the use of fluoxetine to treat depression to 26 years. (*See id.* at 85a). And even after the Federal Circuit's decision, contrary to Lilly's current cries of inequity, Lilly has enjoyed an unduly extended depression monopoly – 23 years instead of 26 years – still 6 years more than the then Congressionally-mandated term. 35 U.S.C. § 154 (1994).

Except to obtain its extended monopoly, there was no reason for Lilly to wait 12 years before requesting a patent on its basic invention. Lilly attempts to explain the 12-year delay by implying that it was distracted by difficulties prosecuting other patent applications. But this excuse is mere makeweight. Parties routinely prosecute multiple patent applications at the same time, and in fact, Lilly did so in this case. During the early 1980s,

Lilly was prosecuting simultaneously at least *five* fluoxetine-related patent applications. (J.A.00280-90; J.A.00291-300; J.A.00740-49; J.A.00320-30; J.A.01069-73; J.A.01387-92). As the Federal Circuit correctly recognized, nothing prevented Lilly from seeking the '549 patent long before 1986. (Lilly App. at 24a n.7).

C. Even After Delaying For 12 Years, Lilly Still Could Have Avoided A Double-Patenting Violation By Filing A Timely Terminal Disclaimer, But It Chose Not To Do So.

Even after delaying the issuance of the '549 patent for 12 years, Lilly still could have avoided the patent's invalidity by filing an appropriate terminal disclaimer before the PTO issued the patent. A terminal disclaimer officially abandons the monopoly-extending portion of the later-issued patent and, thus, avoids double-patenting issues. Lilly chose not to do so here. In fact, Lilly did not offer to file a terminal disclaimer even during six years of double-patenting litigation before the district court and the Federal Circuit.

Instead, Lilly proposes filing a terminal disclaimer for the first time in its certiorari petition before this Court. Even though the matter was directly at issue below – *i.e.*, whether the '549 patent was invalid – Lilly never argued that a post-issuance, post-litigation terminal disclaimer could avoid the patent's invalidity. Instead, Lilly made a strategic decision not to file a terminal disclaimer before now. In an effort to preserve the longest possible monopoly, Lilly chose not to abandon any portion of its monopoly with a terminal disclaimer. Having pursued that strategy and lost, Lilly cannot now, after the Federal Circuit has ruled, raise a terminal-disclaimer issue for the first time in the Supreme Court. It is simply too late.

II. Proceedings Below

A. After An Unusually Thorough Review By The *En Banc* Court, A Unanimous Panel Of The Federal Circuit Held The '549 Patent Invalid For Double Patenting Under "Firmly Establishe[d]" Law.

The Federal Circuit reached its decision in this case after an unusually thorough review of the issues. Ten active judges on the Federal Circuit reviewed the underlying double-patenting issues a total of three times. And with only one possible exception – which is debatable because the Federal Circuit denied Lilly's final rehearing petition with no dissent – no judge has questioned the conclusion that the '549 patent is invalid.

Throughout this litigation, Barr has contended that the '549 patent was invalid for double patenting over each of Lilly's five earlier-expiring fluoxetine patents. In August 2000, the Federal Circuit declared the patent invalid over Lilly's depression patent, which had expired in 1994. The court found that the '549 patent represented an effort by Lilly to "extend the term of exclusivity it enjoyed under [its depression] patent for an additional nine years beyond the statutorily prescribed term." (Lilly App. at 85a).

In response to that decision, Lilly filed a petition for rehearing *en banc*, arguing that there was at least a factual issue over whether the '549 patent was invalid over the depression patent. (*See* Lilly's 1st Reh'g Pet. at 4-7). In addition to its lack of merit, Lilly's purported factual dispute was inconsequential. The panel's reasoning applied with equal force to Lilly's anxiety and hypertension patents, neither of which required the Federal Circuit to wade into any evidentiary issues. Thus, in its opposition to Lilly's petition, Barr suggested that the Federal Circuit avoid Lilly's purported factual dispute by applying the panel's reasoning to either the anxiety or hypertension patent. (*See* Barr's Opp'n to Lilly's 1st Reh'g Pet. at 2).

The Federal Circuit did precisely that. The *en banc* court "vacated the panel's original opinion," and then "reassigned the opinion to the panel for a specific revision of the double patenting section." (Lilly App. at 2a). The panel made that "specific revision" by again holding the '549 patent invalid for double patenting, but this time over the anxiety patent as Barr had suggested. When declaring the later-issued '549 patent invalid over the earlier-issued anxiety patent, the panel stated that "[o]ur case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." (*Id.* at 31a). Before public issuance, the *en banc* court *sua sponte* reviewed the panel's revised opinion. (*Id.* at 2a). Only one judge dissented from among ten active judges – Judge Newman – and she did so in a written opinion that no other judge joined.

In response to the Federal Circuit's second opinion, Lilly filed another petition for rehearing *en banc*, which gave the *en banc* court a third opportunity to review the panel's reasoning. This time, however, Lilly took its cue from Judge Newman by fully developing a statutory prior-art argument that Lilly had earlier raised only in passing. Lilly expanded its earlier one-paragraph analysis of this issue (*see* Lilly Cross-Appellant Br. at 62) into 15 pages of new arguments about the case law and previously uncited legislative history and published PTO policies (*see* Lilly's 2nd Reh'g Pet.). At the Federal Circuit's invitation, Barr filed an opposition fully explaining why Lilly's novel prior-art argument was logically and legally flawed. The Federal Circuit then denied Lilly's second rehearing petition. Notably, after Barr filed its opposition brief, Judge Newman did not renew her dissent. (*See* Lilly App. at 95a-96a). Thus, the denial was unanimous. (*Id.*).

B. In Its Zeal To Resurrect Its Most Important Patent, Lilly Distorts The Record.

In its zeal to resurrect a patent monopoly allegedly worth "$4 billion in sales" (Lilly Pet. at 2), Lilly distorts the record in

three specific ways. First, Lilly not only fails to acknowledge that Judge Newman did not ultimately maintain her dissent, but it also misstates her original dissent. Judge Newman divided her initial dissent into two separate sections, one addressing the prior-art issue now before this Court and the other addressing an "inherency" issue not before the Court. (Lilly App. at 43a-50a). Lilly, unfortunately, quotes from Judge Newman's *inherency* discussion to suggest that the *prior-art* issue is important. (Lilly Pet. at 24).

Second, to imply misleadingly that the disputed issues are somehow important, Lilly refers to the *amicus* support it received in the Federal Circuit. Lilly mentions that "[f]ive *amici*, including the Federal Circuit's own bar association, sought to file briefs supporting Lilly's petition for rehearing of the second opinion." (*Id.* at 12). But Lilly neglects to mention that none of those *amici* focused on Lilly's prior-art argument. They focused on other issues, such as the standard for determining whether to apply a "one-way" or "two-way" double-patenting analysis, an issue not before this Court. In fact, other than Lilly itself, no party has yet shown any interest in the prior-art issue.[2]

Third, to support the notion that the Federal Circuit "was not receptive to suggestions of continued error in its second opinion," Lilly notes that the court declined to accept any of the five proposed *amicus* briefs. (*Id.*). Lilly is telling only half the story. Far from not carefully considering the issues, the Federal Circuit rejected those five *amicus* briefs only because of earlier events that Lilly fails to recite. Since the Federal Circuit's original decision in August 2000, Lilly has made substantial

2. Barr understands, however, that certain parties soon will be filing or seeking leave to file *amicus* briefs in this Court on the prior-art issue – including two organizations that included Lilly as a prominent member called "Intellectual Property Owners Association" and "Biotechnology Industry Organization" (both of which are now seeking leave to file their third *amicus* brief supporting Lilly on yet a third different issue) and five law professors (at least two of whom were formerly employed by law firms that have represented Lilly in this case).

efforts to generate *amicus* support in favor of whatever argument it was then pursuing. Even though Lilly's two rehearing petitions addressed completely different issues, some Lilly-solicited *amici* sought leave to file briefs supporting *both* petitions. The Federal Circuit accepted the *amicus* briefs on the first petition, but only after noting that they were "at the very borderline of denial for leave of filing" because they were "for the most part repetitive of the arguments made by the parties." *Eli Lilly & Co. v. Barr Labs., Inc.*, Nos. 99-1262, 99-1263, 99-1264, 99-1303 (Fed. Cir. Feb. 14, 2001). When Lilly and its allies tried the same tactic again for Lilly's second petition, the Federal Circuit rejected the unhelpful filings.

REASONS FOR DENYING THE WRIT

I. Lilly's Prior-Art Issue Is Not Important.

Lilly's prior-art issue does not warrant Supreme Court review. As this Court has long recognized, "certiorari jurisdiction is designed to serve purposes broader than the correction of error in particular cases . . . ." *Watt v. Alaska*, 451 U.S. 259, 275 n.5 (1981) (Stevens, J., concurring). This Court does not "grant a certiorari to review evidence and discuss specific facts." *United States v. Johnston*, 268 U.S. 220, 227 (1925). Lilly's argument, however, presents a fact-bound issue that never arose before in the 100-year history of double-patenting jurisprudence and likely will never arise again due to a statutory change in the law.

A. Lilly's Prior-Art Issue Never Arose Before.

Far from asserting that its prior-art issue was important to the patent system, Lilly told the Federal Circuit that even after "a review of nearly 500 double patenting decisions," it could not locate even one other case where the issue arose, much less a case that recognized its proposed prior-art exception. (Lilly's 2nd Reh'g Pet. at 7).

This is not surprising because in most cases, unlike here, applicants seek patents on their basic inventions *before* obtaining patents on later-developed improvements, thus avoiding double-patenting problems. And even when unusual delays result in the issuance of the improvement patent first, a prior-art issue normally would never surface because of the lack of any relevant public disclosure. Such disclosures are unlikely because, for the improvement patent to issue first, the patent owner normally would need to request the improvement patent at the same time or at least soon after requesting the basic patent. As a practical matter, the lack of any significant lag between the two requests prevents interim public disclosures.

Here, the prior-art issue arose only because of Lilly's strategic 12-year delay in seeking a patent on its basic invention. Lilly filed an application that disclosed its purported basic invention in 1974, but failed to request a patent on the invention until 1986. (Lilly App. at 4a, 7a-8a and 24a n.7). During that 12-year delay, Lilly sought related patents through other applications containing identical text, which resulted in the public disclosure of Lilly's basic invention when the PTO issued Lilly's depression patent in 1977. (J.A.00291-300). Lilly's continued delay after 1977 then enabled it to develop its anxiety invention, request an anxiety patent in 1983, and obtain the anxiety patent all before obtaining a patent on a basic invention it developed 12 years earlier. (J.A.00312-313; J.A.00320-330). Any change in that sequence of events would have avoided the prior-art issue altogether.

Barr's exhaustive research confirms the rarity of Lilly's prior-art issue. After reviewing virtually every double-patenting decision since 1894, Barr located only one other case where one patented invention was "statutory prior art" to the other. *See In re Borg*, 392 F.2d 642, 643 (C.C.P.A. 1968). In that case, contrary to Lilly's argument, the Court of Customs and Patent Appeals recognized that double patenting existed (curable only through a terminal disclaimer filed before the patent's issuance)

even though one claimed invention "seemingly enjoy[ed] the status of statutory prior art" to the other. *Id.* The patent owner, however, never asserted any purported prior-art exception and, thus, the court never addressed the issue.

B. Lilly's Prior-Art Issue Likely Will Never Arise Again.

A 1995 change in the law makes it exceedingly unlikely that Lilly's prior-art issue will ever arise again. Before 1995, a patent's 17-year term was measured from the date of its issuance. This created fertile ground for double-patenting issues, particularly when an applicant delayed the issuance of its basic patent, which effectively could extend the term of any earlier-issued improvement patent. Under the new law, however, patents have 20-year terms measured from the earliest application that the patentee relies on for a priority date. *See* 35 U.S.C. § 154 (2001); *Abbott Labs v. Novopharm Ltd.*, 104 F.3d 1305, 1308 (Fed. Cir. 1997). By tying the patent's expiration date to the earliest priority date, the statute prevents patent owners from using post-application delay and later expiration dates to obtain monopoly extensions. Here, for example, the '549 patent would have expired in 1994 under the new law because Lilly relied on the original 1974 application for the patent's priority date.

As Lilly has recognized, the new law prevents its prior-art issue from arising again. When arguing against a standard double-patenting analysis (called the "one-way test"), Lilly acknowledged below that the new law already "remed[ied]" the problems arising from "inordinate delays in the PTO":

> A better alternative to a one-way test for remedying this problem would be legislation dealing with the consequences of inordinate delays in the PTO. That, of course, has now happened, through legislative enactment of the 20-year term from the effective filing date rather than 17 years from the date of issue. 35 U.S.C. § 154 (1998).

(Lilly Cross-Appellant Br. at 70). This change in the law, by itself, warrants the denial of Lilly's petition for certiorari. *See Morris v. Weinberger*, 410 U.S. 422 (1973) (dismissing writ of certiorari as improvidently granted where Congress amended disputed statutory provisions); *Rice*, 349 U.S. at 73-80 (dismissing writ of certiorari as improvidently granted after learning of corrective legislation that "bars the ultimate question presented in this case from again arising"); *Dist. of Columbia v. Sweeney*, 310 U.S. 631 (1940) (denying certiorari "in view of the fact that the tax is laid under a statute which has been repealed and the question is therefore not of public importance"); Robert L. Stern, *Denial of Certiorari Despite A Conflict*, 66 Harv. L. Rev. 465, 470 (1953) (noting that even a clear circuit conflict "will not necessarily result in the granting of certiorari if the issue is no longer a live one," such as when "the statute upon which the controversy rested ha[s] expired or been amended in a manner which would prevent the problem from arising in the future").

This new legislation also refutes Lilly's suggestion that the "Federal Circuit's decision undermines the very spirit of innovation that is the touchstone of patent law." (Lilly Pet. at 25). Lilly is speculating that future applicants will delay seeking improvement patents until after their basic patents issue to avoid the risk of double patenting. (*Id.* at 26). According to Lilly, applicants will be concerned about the possibility of "substantial delay in the issuance of a patent on a groundbreaking basic invention," which Lilly asserts will create double-patenting problems in the event the improvement patent issues first. (*Id.*). But that purported concern is not relevant as of 1995 – patent monopolies are no longer measured from the date of the "issuance of a patent" and, therefore, "substantial delay[s]" before issuance cannot possibly create any double-patenting issues. Consequently, contrary to Lilly's argument, the Federal Circuit decision's does not create a reason to delay the request for an improvement patent.

C. Lilly's Prior-Art Issue Is Not Even Important To The Outcome Of *This* Case.

Lilly's prior-art argument will not even change the outcome of *this* case and, thus, is wholly unimportant. Barr argued below that the '549 patent was invalid over each of Lilly's five earlier-expiring fluoxetine patents. The Federal Circuit held the '549 patent invalid over the anxiety patent alone and, thus, never reached the other four patents. Of those four patents, Lilly's prior-art argument applies only to Lilly's hypertension patent. Thus, even if the argument had any merit, the '549 patent would remain invalid over the remaining three patents.

In sum, Supreme Court review is not warranted for a fact-bound double-patenting issue that Lilly argues never arose before and that, based on a 1995 change in the law, likely will never arise again, particularly considering that the issue will not even impact the validity of Lilly's own patent.

II. The Federal Circuit Correctly Rejected Lilly's Prior-Art Argument.

Lilly ultimately is seeking mere error correction from this Court, which is not the function of certiorari jurisdiction. In any event, there is no error to correct because the Federal Circuit properly rejected Lilly's prior-art argument. Stripped of all of its rhetoric, Lilly is arguing that the Federal Circuit's decision will adversely impact the patent system based on the notion that the court somehow changed the law. But the Federal Circuit itself did not suggest it was changing the law in any way. Instead, as demonstrated below, the court correctly applied a straightforward rule in the very same way the rule has been applied since 1894.

A. Far From Contradicting The Statutory Regime, The Federal Circuit's Decision Was Compelled By The Statutory Limit On Patent Terms.

The Federal Circuit relied on 100 years of uniform case law to find the '549 patent invalid for double patenting. (Lilly App. at 22a-32a). Lilly argues that the court nevertheless erred because its decision purportedly "contradicts the statutory regime for determining separate patentability." (Lilly Pet. at 12). Lilly contends that because its anxiety invention was purportedly patentable over the '549 invention under Section 103 of the Patent Code, which requires non-obviousness over the statutory prior art, the '549 patent is immune from a standard double-patenting analysis.

But a Section 103 analysis and a double-patenting analysis are separate and independent. Section 103 sets forth only one of *many* independent requirements for obtaining a patent. As the patent statute explains, a party who invents a "new and useful process . . . may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (2001). In addition to Section 103, one such "condition and requirement" is compliance with the statutory and constitutional limit on the term of a patent monopoly, which is what mandates the rule against double patenting. *See* U.S. Const., art. I, § 8, cl. 8 (recognizing that Congress shall have the power "[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing *for limited [t]imes* to . . . [i]nventors the exclusive [r]ight to their . . . [d]iscoveries") (emphasis added); 35 U.S.C. § 154 (1994) (setting specific limits on the term of a patent monopoly).

Because they are separate and independent requirements, Lilly's effort to manufacture a "conflict" between a Section 103 analysis and a double-patenting analysis is illogical. Section 103 and the double-patenting doctrine have "distinct and separate" purposes, thus "requiring different inquiries and representing mutually exclusive grounds for rejecting claims." *In re Bowers*, 359 F.2d 886, 889 (C.C.P.A. 1966). Along with

Section 102, Section 103 determines whether the claimed invention is patentable over the statutory prior art. The double-patenting doctrine, on the other hand, determines whether the applicant is improperly extending its patent monopoly beyond the statutorily-prescribed term. It embodies the longstanding conclusion that – regardless of whether the claimed invention is unobvious over the statutory prior art – applicants cannot use their control over patent prosecution to obtain an extended monopoly. *See Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 201 (1894); *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993); *In re Blattner*, 245 F.2d 491, 494 (C.C.P.A. 1957).

B. To Enforce The Statutory Limit On Patent Terms, The Federal Circuit Applied A Century-Old Double-Patenting Rule In A Straightforward Way.

Far from contradicting the "statutory regime," the Federal Circuit's decision applied a standard double-patenting rule that has remained undisturbed since 1894. Over a century ago in *Miller*, this Court held that, when obtained by the same applicant, a "second patent . . . containing a broader claim, more generical in its character, than the specific claims, contained in [a] prior patent, is . . . void." 151 U.S. at 198. That rule exists, according to this Court, because otherwise the "new and later patent . . . would operate to extend or prolong the monopoly beyond the period allowed by law." *Id.* at 198 (citing *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819)).

In the century since *Miller*, courts continuously have enforced the statutory limits on patent monopolies by applying the same rule, which is "[p]erhaps the most frequently cited statement of the rule" against double patenting. *Pierce v. Allen B. Du Mont Labs., Inc.*, 297 F.2d 323, 327 (3d Cir. 1961). In 1957, the Court of Customs and Patent Appeals surveyed the controlling authority and confirmed that "an applicant who accepts a patent containing only claims which are limited to a single species cannot thereafter obtain a second patent containing

claims generic to that species." *Blattner*, 245 F.2d at 494. The court explained that this "sound" rule enforces the statutory limits on patent monopolies:

> [W]ithholding of the presentation of generic claims in one application until after a patent has been issued on another application containing claims limited to a species of the genus would make some extension of monopoly inevitable, and a very considerable extension probable if a second patent containing generic claims, were granted.

Id.

As recently as 1993, the Federal Circuit again cited *Miller* when confirming the long-settled law: "A second application – 'containing a broader claim, more generical in its character than the specific claim in the prior patent' – typically cannot support an independent valid patent." *Goodman*, 11 F.3d at 1053 (quoting *Miller*). The Federal Circuit explained that allowing an applicant to obtain the broader claim under such circumstances "would extend the exclusionary right past the 17-year limit mandated by Congress" in violation of "Supreme Court precedent." *Id.*; *accord James v. Campbell*, 104 U.S. 356, 382 (1881) ("It is hardly necessary to remark that the patentee could not include in a subsequent patent any invention embraced or described in a prior one granted to himself. . . ."); *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998) (holding "all of the genus claims" invalid based on double patenting over earlier-patented "species claims"); *In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982) (recognizing case as "genus-species relation" and holding "generic" claims invalid based on double patenting over earlier patented "specific" claims).

Here, the Federal Circuit applied the century-old *Miller* rule in a straightforward way. Lilly first accepted a species patent (the anxiety patent) and later accepted a genus patent (the '549

patent). As the Federal Circuit correctly recognized, this is a classic example of double patenting. (Lilly App. at 22a–32a).

C. The Courts Have Already Addressed Lilly's "Unfairness" Concerns With A Double-Patenting Exception Called The "Two-Way Test," Which Lilly Ignores And Which Does Not Apply Here.

Because it does not dispute that the '549 patent is invalid under *Miller*, Lilly is forced to ask this Court to create a brand-new exception to the century-old *Miller* rule. Lilly contends that this proposed exception – the prior-art exception – is necessary to avoid unfairness when there is a "substantial delay in the issuance of a patent on a groundbreaking invention," which may cause an applicant's later-filed improvement or species patent to issue first. (Lilly Pet. at 26).

But there is no need to create a *new* exception to address this concern because such an exception *already exists* – the "two-way test." Courts normally apply a one-way double-patenting analysis, where the only relevant inquiry is whether the later-issued patent (here, the '549 patent) is patentable over the earlier-issued patent (here, the anxiety patent). The two-way test is a "narrow exception" to that standard analysis, under which courts also consider the reverse inquiry by asking whether the *earlier-issued* patent is patentably distinct from the *later-issued* patent. *Berg*, 140 F.3d at 1432.

But the two-way exception applies only in the "special circumstances" when the PTO – not the applicant – delays the issuance of a basic patent. *Id.* It is designed "to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing." *Id.*; *accord In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997) (two-way exception does not apply because applicant "had significant control" over when the applications would be filed and "orchestrated the rate of

prosecution"); *Goodman*, 11 F.3d at 1053 (two-way exception does not apply because "PTO actions did not dictate the rate of prosecution" and applicant "chose to file a continuation and seek early issuance of the narrow species claims"); *In re Braat*, 937 F.2d 589, 593-94 (Fed. Cir. 1991) (applying two-way exception only because the applicant did not have "complete control" over "the rate of progress of the applications through the PTO" and finding that it was "not [the applicant's] fault that the [more specific] claims . . . issued first").

Thus, an exception already exists to protect patent owners from double patenting when the delay is not their fault. The Federal Circuit correctly held, however, that this exception does not apply here because Lilly – not the PTO – was responsible for delaying the '549 patent's issuance. (Lilly App. at 24a n.7). When an applicant exercises control over the order in which its patents issue, the courts consistently have declined to apply the two-way exception. In *Berg*, for instance, the Federal Circuit explained that the two-way exception does not apply "under settled case law" when an applicant files "genus claims long after the species claims even though the two were invented at nearly the same time or the genus claims were invented first . . ." 140 F.3d at 1434 n.6. Here, Lilly did exactly that, filing its "genus claim[ ]" to serotonin blocking three years after its "species claim" to anxiety treatment, "even though . . . the genus claim[ ] [was] invented first." Thus, Lilly exercised complete control over the order of patent issuance, which precludes the two-way exception. *See* 3 Donald S. Chisum, *Chisum on Patents* § 9.03[2][c] (2001) (the two-way exception does not apply when "the later issuing generic claim [was] filed after the application" containing the species).

Even though its certiorari petition does not mention the two-way exception, much less argue that it applies, Lilly relies heavily on one of the earliest examples of that exception – *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712 (6th Cir. 1897). (*See* Lilly Pet. at 15-17). In *Ohio Brass*, the applicant

applied for its basic patent "more than a year before" applying for its improvement patent. 80 F. at 724. The PTO nevertheless issued the patents in the reverse order, with the improvement patent issuing before the basic patent. *Id.* The Sixth Circuit thus declined to find double patenting, noting that this was a case "where the delay in issuing of the patent for the main invention cannot be charged to the laches . . . of the patentee . . . ." *Id.* Here, in contrast, the delay in issuing the patent for the main invention *can* be charged to Lilly, which precludes application of the two-way exception under *Ohio Brass's* reasoning.

Lilly nevertheless argues that the Federal Circuit should not have considered Lilly's delay because Barr did not assert a laches defense. (Lilly Pet. at 23). But regardless of whether Barr asserted a laches defense, Lilly's delay was indisputably relevant to the Federal Circuit's rejection of the two-way exception – an issue that Lilly self-consciously ignores. Lilly similarly asserts that the Federal Circuit erred because its *earlier-issued* anxiety patent was allegedly patentable over its *later-issued* basic patent. But this backwards analysis is relevant *only* under the two-way exception. Because it does not contend that the two-way exception applies, Lilly's argument is manifestly irrelevant under a century of settled law.

D. There Is No Rational Justification For Lilly's Proposed Prior-Art Exception, Which Contradicts The Purpose Of The Rule Against Double Patenting.

Finally, Lilly's proposed prior-art exception would defeat the purpose of the rule against double patenting. Whether or not its subject matter is prior art to the species patent, a later-issued genus patent still would "operate to extend or prolong the [earlier species] monopoly beyond the period allowed by law." *Miller*, 151 U.S. at 198 (citing *Odiorne*). And "[e]ffectively extending the patent term . . . is precisely the result that the doctrine of obviousness-type double patenting was created to prevent." *Berg*, 140 F.3d at 1435. While an exception to the

double-patenting doctrine makes sense when the PTO is to blame for the extended monopoly – hence, the two-way exception – there is no good reason for permitting such extensions when the patentee is responsible.

In fact, Lilly's proposed exception affirmatively would encourage monopoly extensions. This case proves the point. Once its genus invention became prior art to the anxiety and hypertension patents – thus avoiding double patenting under the proposed exception – Lilly could have delayed its genus patent's issuance with impunity. Indeed, it could have delayed the '549 patent's issuance until just before the anxiety patent expired, thereby obtaining 34 years of species' exclusivity. Thus, adopting Lilly's prior-art exception would make the rule against double patenting a dead letter and directly undercut the thrust of the limited terms of patents mandated by Congress.

The lack of any policy justification for a new prior-art exception is confirmed by the extraordinary breadth of Lilly's arguments, which, if accepted, would logically require this Court to overrule the double-patenting doctrine. Lilly contends that it constitutes unfair "discriminat[ion] against the owner of the basic patent" to invalidate the '549 patent over the anxiety patent because, if they were owned by separate parties, both patents might have been valid. (Lilly Pet. at 24-25). But that is almost *always* the case in double patenting. In every case where a later-issued genus patent is invalid for double patenting over an earlier-issued species patent, the two patents could be valid if separately owned. This only makes sense. Double patenting prevents a *single applicant* from obtaining an extended patent term through its control over patent prosecution – an issue that does not exist when the applications are separately owned. *See Miller*, 151 U.S. at 198; *Berg*, 140 F.3d at 1434 n.6; *Goodman*, 11 F.3d at 1053; *Blattner*, 245 F.2d at 494.

Lilly similarly argues – repeatedly and without citation – that the Federal Circuit erred by focusing "on the order in which the . . . *patents issued*" rather than "on the order in which the

two *inventions were discovered.*" (*See, e.g.*, Lilly Pet. at 5 (emphasis in original)). If that were error, courts have been committing the same error every time they found double patenting for the last 100 years. Double patenting *always* focuses on patent issuance dates because the doctrine is designed to prevent undue monopoly extensions, a question that was determined by patent issuance dates before the change in the law in 1995. *See, e.g.*, *Berg*, 140 F.3d at 1437 (conducting double-patenting analysis by focusing on the order the patents issued); *Goodman*, 11 F.3d at 1053 (same); *Blattner*, 245 F.2d at 494 (same).

In addition to generalized attacks that apply broadly to the entire double-patenting doctrine, Lilly attempts to justify its proposed exception with tortured logic that cannot withstand even mild scrutiny. Lilly contends that the rule against double patenting cannot "intrude into [an] area where Congress has supplied the complete test for separate patentability in the statutory scheme of Title 35." (Lilly Pet. at 19). But Title 35 does *not* supply the "complete test" for the *relevant* inquiry. Lilly argues that a public disclosure made Section 103 applicable to determining whether the *earlier-issued* anxiety patent was patentably distinct from the *later-issued* '549 patent. But that inquiry is relevant only under the inapplicable two-way test. No public disclosure made Section 103 relevant to the proper inquiry under the one-way test, *i.e.*, whether the *later-issued* '549 patent was patentably distinct from the *earlier-issued* anxiety patent. Thus, even under Lilly's own illogical argument, the double-patenting doctrine applies in this case.

In the end, Lilly argues that the Federal Circuit changed the law only by ignoring a double-patenting rule that has remained undisturbed since 1894. The Federal Circuit merely applied that century-old rule in a straightforward way. As always, even without a terminal disclaimer, a later-issued genus patent will be valid over an earlier-issued species patent as long as the applicant, unlike here, files the genus claims first and is not responsible for reversing the order of patent issuance.

III. The Terminal-Disclaimer Issue Does Not Merit Supreme Court Review.

A. Not Even Lilly Contends That The Terminal-Disclaimer Issue Satisfies Any Of The Traditional Bases For Supreme Court Review.

Nothing about Lilly's second question presented – the terminal-disclaimer issue – merits Supreme Court review. Not even Lilly itself asserts that the question satisfies any of the traditional bases for Supreme Court review. It cites no circuit conflict, no contrary Supreme Court precedent, and no constitutional issue. Indeed, Lilly never even asserts that the issue is somehow important to anyone other than the litigants in this case. As evidenced by the fact that it addressed the issue in a mere footnote, the Federal Circuit certainly did not consider the issue important. This lack of importance is confirmed by Lilly's failure – despite purportedly reviewing nearly 500 double-patenting decisions – to cite even one other case addressing whether a post-judgment terminal disclaimer could resurrect an invalid patent.

B. Lilly Waived Its Terminal-Disclaimer Argument, Which Is Rife With Never-Litigated Factual Issues, By Intentionally Declining To Raise It Before The Federal Circuit.

Supreme Court review also is inappropriate because Lilly waived its terminal-disclaimer argument. During six years of litigation, Lilly never attempted to file a terminal disclaimer, not even when filing its last petition for rehearing and not even on a contingent basis. The Federal Circuit merely addressed this issue *sua sponte* in a footnote. When an appellate court *sua sponte* addresses an issue the petitioner never raised, this Court typically will exercise its certiorari jurisdiction only "where the issue is . . . in a state of evolving definition and uncertainty and one of importance to the administration of federal law." *See Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1099 n.8 (1991)

(citations and internal quotation marks omitted); *accord E.E.O.C. v. F.L.R.A.*, 476 U.S. 19, 24 (1986) ("Our normal practice, from which we see no reason to depart on this occasion, is to refrain from addressing issues not raised in the Court of Appeals."). Lilly makes no effort to make any such showing, which it cannot do because this is the first and only case to ever address the issue.

Undeveloped factual issues also counsel against Supreme Court review. Because Lilly is raising the terminal-disclaimer issue for the first time in the Supreme Court, the parties never developed a record on the issue below. Possible factual issues abound, including, for instance, issues relating to the doctrine of equitable estoppel, which would preclude Lilly's belated effort to file a terminal disclaimer. Under that fact-intensive doctrine, the delayed assertion of an alleged property right is barred upon proof of misleading conduct, action taken in reliance on that conduct, and resulting prejudice. *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 59 (1984); *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1557 (Fed. Cir. 1996).

Here, Barr argued for six years that the '549 patent was invalid for double patenting and during that whole time, Lilly never filed a terminal disclaimer. (*See* Lilly Pet. at 28). That was a strategic decision. In fact, Lilly did the exact opposite – it sought to *preserve* its extended monopoly by disclaiming the earlier-expiring anxiety and hypertension patents. Thus, along with the rest of the pharmaceutical industry, Barr reasonably concluded that Lilly did not intend to file a terminal disclaimer. As a result – after the Federal Circuit's decision, but before Lilly proposed filing a terminal disclaimer – Barr sold over $200 million of generic fluoxetine and, therefore, would be prejudiced severely if Lilly now were permitted to make new arguments about the validity of the '549 patent. Because Lilly never raised the issue below, there is no evidentiary record whatsoever on this fact-intensive equitable defense. This alone

warrants the denial of Lilly's certiorari petition. *See Mishkin v. New York*, 383 U.S. 502, 512-13 (1966) (dismissing certiorari as improvidently granted where there was "neither evidence nor findings" on relevant underlying issues and, thus, the issues were "not presented by the record with sufficient clarity to require or justify their decision").

Denial additionally is warranted because the terminal-disclaimer issue is not yet ripe for judicial review. Nothing in the record indicates that Lilly *already* has filed a terminal disclaimer. Lilly's petition does not represent that it has done so and, instead, indicates only that it is willing to do so. (Lilly Pet. at 27-28). Until it files such a terminal disclaimer with the PTO, however, Lilly's terminal-disclaimer argument is not ripe for adjudication. Certiorari jurisdiction is not designed for this Court to render advisory opinions about the legal effect of an action that a litigant may or may not decide to take in the future. "It has long been this Court's considered practice not to decide abstract, hypothetical or contingent questions . . . ." *United Pub. Workers of Am. v. Mitchell*, 330 U.S. 75, 90 n.22 (1947) (internal quotation marks omitted). Thus, were this Court "to pass upon the purely artificial and hypothetical issue tendered" by Lilly's petition, it would "not only in effect be rendering an advisory opinion but also lending [itself] to an unjustifiable intrusion upon the time of this Court." *Conway v. Cal. Adult Auth.*, 396 U.S. 107, 110 (1969).

C. Lilly's Terminal-Disclaimer Argument Is Not Even Important To The Outcome Of *This* Case.

In addition to its lack of general importance, the terminal-disclaimer issue is not even important to the outcome of *this* case. Lilly seeks to disclaim the portion of the '549 patent term extending beyond May 2003, which was the scheduled expiration date for Lilly's anxiety patent. But even if Lilly were permitted to do so, the '549 patent would remain invalid over

its hypertension patent, which already expired in 2000. (J.A.00304-308; Lilly Pet. at 28 n.10). In fact, Lilly told the Federal Circuit that the anxiety and hypertension patents present "virtually the identical" double-patenting issues and then confirmed that fact by always arguing the patents together. (Lilly Cross-Appellant Br. at 24).

Consistent with Lilly's representation, the Federal Circuit's holding applies equally to both the anxiety and hypertension patents. The court found the '549 patent invalid over the anxiety patent because "[s]erotonin uptake inhibition is a natural biological activity that occurs when fluoxetine hydrochloride is administered to an animal, such as a human, for *any* purpose, including the treatment of anxiety." (Lilly App. at 26a (emphasis added)). "[A]ny purpose" also includes the treatment of hypertension. Thus, under the Federal Circuit's reasoning and express holding, the '549 patent is invalid for double patenting over *both* the anxiety *and* hypertension patents. Consequently, permitting Lilly now to disclaim the term of the '549 patent extending beyond the anxiety patent would be meaningless. The patent would remain invalid over the already-expired hypertension patent.

D. The Federal Circuit Correctly Recognized That Lilly Could Not Resurrect The '549 Patent With A Post-Judgment Terminal Disclaimer.

In any event, the Federal Circuit was right on the merits. Lilly asserts the court's decision was "wholly irrational and unfair" because, according to Lilly, the controlling statute gives it a right to resurrect its patent with a post-judgment terminal disclaimer. But the statute addresses no such issue. *See* 35 U.S.C. § 253 (2001). The statute permits patentees to "disclaim" a portion of their patent monopoly, but does not state that doing so will avoid a judicial finding that a patent is invalid for double patenting. *Id.* And none of the cases that Lilly cites addresses terminal disclaimers filed after a final judgment holding the patent invalid.

Far from holding that a post-*judgment* disclaimer will cure a double-patenting violation, the law does not even hold that a post-*issuance* disclaimer will do so. According to the leading patent treatise, "[n]o decision considers squarely whether a terminal disclaimer entered after the issuance of the second patent will cure a double patenting objection." Chisum, *supra*, § 9.04 [4][b]. Under analogous circumstances, however, the Federal Circuit rejected efforts to adjust the term of a monopoly after the patent issued in *Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305, 1308 (Fed. Cir. 1997). In that case, Abbott initially claimed priority based on the filing date of an early application. *Id.* But when the circumstances later changed to make it advantageous to do so, Abbott attempted to obtain patent protection for 20 years from the date of a later-filed application. *Id.* The Federal Circuit rejected the effort, explaining that Abbott's initial decision was made "to receive the potential benefits" of the earlier date and, thus, "cannot be disregarded simply because it subsequently found that the later filing date would be more advantageous." *Id.*

Here, Lilly decided against filing a terminal disclaimer to obtain an extended monopoly. That choice cannot now "be disregarded simply because" Lilly's attempt to obtain an extended monopoly failed, particularly considering that the '549 patent's value depended partly on its *scheduled* expiration date. Lilly's decision to retain the scheduled expiration of the '549 patent may have "forced [its competitors] into decisions they would not have made had the terminal portion of . . . the patent[] been disclaimed promptly," including decisions relating to product selection and the allocation of research resources. Chisum, *supra*, § 9.04 [4][b] (internal quotation marks omitted).

And even if a post-*issuance* disclaimer could cure a double-patenting violation, a post-*judgment* disclaimer certainly cannot. Any such notion violates the "deeply rooted . . . 'presumption of regularity' that attaches to final judgments, even when the question is waiver of constitutional rights." *Daniels v. United*

States, 532 U.S. 374, 121 S. Ct. 1578, 1583 (2001) (citation and internal quotation marks omitted). Here, in a case with no constitutional implications, Barr asked the Federal Circuit to declare the '549 patent invalid. It is too late now, *after* the Federal Circuit declared the patent invalid, for Lilly to make a new argument that allegedly would "preserve the validity of the ['549] patent." (Lilly Pet. at 28); *accord United States v. Olano*, 507 U.S. 725, 731 (1993) ("No procedural principle is more familiar to this Court than that a constitutional right . . . may be forfeited in criminal as well as civil cases by the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it.") (citation and internal quotation marks omitted).

CONCLUSION

In the end, Lilly's arguments in favor of certiorari are wholly insubstantial. As Lilly correctly conceded below, the circumstances of this case are unique and unlikely to ever occur again. Lilly thus is asking this Court to grant certiorari to create case-specific rules that will benefit nobody but Lilly. In fact, for both of its questions presented, Lilly fails to cite even one other case addressing the specified issue. Particularly considering that a 1995 change in the law now eliminates most double-patenting issues, Lilly's proposed rules likely would never apply in any other case in the future. In any event, the Federal Circuit correctly resolved the disputed issues as confirmed by Lilly's refusal to squarely face the long-settled law compelling the court's decision. Thus, the Court should deny Lilly's petition.

Respectfully submitted,

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